UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

| ELLEN WHITFORD, |) |
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| Plaintiff, |) Civil Action No:) 17-cv-2637 (PGS)(LHG) |
| v. |)) MEMOD ANDUM |
| HORIZON BLUE CROSS BLUE SHIELD OF NEW JERSEY, |) MEMORANDUM) AND) ORDER |
| Defendant. |))) |
| |) |

Presently before the Court are cross-motions for Summary Judgment by Plaintiff Ellen Whitford and Defendant Horizon Blue Cross Blue Shield of New Jersey (ECF Nos. 14, 16). For the reasons discussed herein, BCBS's Motion for Summary Judgment is granted.

BACKGROUND

This case arises from BCBS's refusal to authorize a particular treatment to Plaintiff, finding the procedure experimental. Plaintiff is a 64 year old woman, who works as a school nurse at The Rugby School, which provides a fully insured Horizon OMNIA plan. ("BCBS's Statement of Undisputed Facts [SUF]" at ¶¶ 1-2; ECF No. 1-2, "Plan").

Like most insurance plans, the Plan here does not provide benefits for out-of-network services. (*Id.* at ¶ 3). Moreover, the Plan requires covered individuals to first receive BCBS's authorization before receiving particular services or treatment. (Plan at 100-06). Under this "utilization review," a "plan administrator reviews a procedure before it is performed to determine whether it is 'medically necessary and appropriate' for treatment of the member's condition." (SUF at ¶ 8). The Plan also grants BCBS discretion in reviewing benefits claims. The Plan limits payment for benefits for "[s]ervices, in [BCBS's] judgment, are at the proper level of care" and

reserves BCBS with "the right to require that care be rendered in an alternate setting as a condition of providing payment for benefits," if it "determines that a more cost-effective manner exists." (*Id.* at 74, 75).

The Plan also states that BCBS is to determine what is considered "medically necessary and appropriate" under the program. (Plan at 100). Notably, the services deemed to be "Experimental or Investigational Technology" are not considered medically necessary and appropriate. (*Id.* at 35). Under the Plan, a service is considered experimental or investigational if it fails to meet any of the following tests:

- a. The Technology must either be: (a) approved by the appropriate federal regulatory agency and have been in use for the purpose defined in that approval; or (b) proven to Horizon BCBSNJ's satisfaction to be the standard of care. . . .
- b. There must be sufficient proof, published in peer-reviewed scientific literature, that confirms the effectiveness of the Technology. That proof must consist of well-designed and well-documented investigations. But, if such proof is not sufficient or is questionable, Horizon BCBSNJ may consider opinions about and evaluations of the Technology from appropriate specialty advisory committees and/or specialty consultants.
- c. The Technology must result in measurable improvement in health outcomes, and the therapeutic benefits must outweigh the risks, as shown in scientific studies. "Improvement" means progress toward a normal or functional state of health.
- d. The Technology must be as safe and effective as any established modality. (If an alternative to the Technology is not available, Horizon BCBSNJ may, to determine the safety and effectiveness of a Technology, consider opinions about and evaluations of the Technology from appropriate specialty advisory committees and/or specialty consultants.)
- e. The Technology must demonstrate effectiveness when applied outside of the investigative research setting.

(Id. at 35). The Plan also provides a three-level appellate process, for which covered individuals can challenge Adverse Benefit Determinations. (Id. at 129). This process consists of: (1) "an informal internal review by Horizon BCBSNJ"; (2) "if the initial decision is upheld, a formal

second level internal review by Horizon BCBSNJ"; and (3) an external appeal presided by the Independent Utilization Review Organization (hereinafter, "IURO"), which is binding on both parties. (*Id.* at 130-33). An external appeal is conditioned on first exhausting the first two internal reviews. (*Id.* at 133).

In any event, on August 6, 2016, Plaintiff suffered an injury to her left elbow, the pain of which has affected her ability to use her left hand and perform everyday tasks. (Amended Complaint at ¶¶ 3, 5). In August and September 2016, Plaintiff consulted with Dr. J. Saleh, an innetwork provider, who opined that she needed complex elbow reconstructive surgery and referred her to Dr. Michael Hausman, who handles such cases. (*Id.* at ¶ 6). The following month Dr. Hausman, an out of network provider, recommended that Plaintiff receive "combined ligament and radiocapitellar reconstruction" of her left elbow. (*Id.* at ¶ 10). The procedure, known as interposition anthroplasty, also required the use of an internal joint stabilizer device, which includes a base plate with three screws, a connecting arm, a locking joint, a boom arm and an axis pin. (*Id.* at ¶ 11). Plaintiff seeks to have this device inserted into her left elbow. This is a relatively new and innovative device that provides temporary stabilization of the elbow joint after chronic elbow dislocation. A surgeon employs an open lateral approach, to insert the device.

After consulting with Plaintiff, on November 10, 2016, Dr. Hausman wrote to BCBS to receive preauthorization to perform the described procedure. (SUF at ¶ 19). On December 16, 2016, BCBS denied Dr. Hausman's request, finding the proposed procedure to be "experimental or investigational." (ECF No. 9-2, "December 16, 2016 Letter"). Specifically, the letter explained that "the use of internal joint stabilizer in elbow reconstruction is considered investigational. . . . There is insufficient literature to support the use of the requested device." (*Id.*). The letter also provided Plaintiff with two in-network elbow surgeons and noted that Plaintiff may appeal this

determination. (*Id.*). In response, Dr. Hausman wrote again to BCBS, on December 22, 2016, asking it to reconsider its initial determination, and approve the proposed procedure. (SUF at ¶ 22).

Understanding this letter to constitute an appeal, on January 12, 2017, BCBS sent Plaintiff a letter, upholding the denial of preauthorization. (ECF No. 6-1, "January 12, 2017 Letter" at 6-9). In arriving at its conclusion, BCBS relied on an independent medical expert opinion, which determined that the proposed procedure remained investigational. (*Id.* at 8). The letter also acknowledged Plaintiff's right to a second level appeal. (*Id.* at 7). On January 18, 2017, Plaintiff initiated a second level appeal with Horizon's Member Appeals Committee, which convened on January 25, 2017. (Amended Complaint at ¶ 22). In a letter dated January 27, 2017, the Committee informed Plaintiff that it had upheld the denial of preauthorization, again concluding that the proposed procedure was deemed investigational or experimental. (ECF No. 9-5, "January 27, 2017 Letter"). The letter also advised Plaintiff of her right to initiate an external appeal. (*Id.*).

On January 31, 2017, Dr. Hausman, on Plaintiff's behalf, wrote one final letter in support of Plaintiff's appeal. (SUM at ¶ 30). Consistent with its external appeals process, BCBS referred the matter to Permedion, an IURO, for review. (*Id.* at ¶ 31). On February 10, 2017, BCBS wrote to Plaintiff to inform her that Permedion affirmed BCBS's denial of preauthorization. (ECF No. 9-6, "February 10, 2017 Letter"). Permedion's decision was based on a recommendation prepared by Dr. Anthony Beisler, an independent board certified orthopedic surgeon. (*Id.* at 8-14). In his February 8, 2017 recommendation, Dr. Beisler found, consistent with BCBS's previous determinations, that "the use of a specific internal joint stabilizer device . . . is experimental/investigational for the treatment of [Plaintiff's] condition, and as such, is not medically necessary[.]" (*Id.* at 12). Dr. Beisler explained that the use of such a device "is a new

concept and only recently published in peer reviewed literature and a few articles." (*Id.*). In addition, he noted that, "this procedure is still not recognized by the Orthopedic Surgery community at large as a standard of care. It is still early in the clinical experience and is considered experimental/investigational." (*Id.*). Consistent with Permedion's determination, BCBS affirmed its denial of preauthorization.¹

After the administrative record closed, in April 2018, Plaintiff submitted a message from Mr. William Perugini of Skeletal Dynamics. (ECF No. 33 at 4). In this message, Mr. Perugini claims that the use of internal joint stabilizer devices "has been overwhelmingly accepted very positively by orthopedic elbow specialists and hospitals alike." (*Id.*). There is also a letter from Dr. Miachael N. Nakashian, M.D., of Brielle Orthopedics, who indicates that the device is "being used throughout the United States. . ." (*Id.* at 2). However, neither of these letters are a part of the record.

Presently, Plaintiff brings this motion, seeking for the Court to authorize the requested procedure. Defendant cross-moves for Summary Judgment since BCBS's denial of preauthorization was not arbitrary or capricious.

LEGAL STANDARD

Summary judgment is appropriate under Federal Rule of Civil Procedure 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett,

At one point, I requested that BCBS review the status of the proposed medical procedure and device, because over a year had elapsed since Permedion's determination. Often, medical practices change rapidly when new devices are developed. BCBS followed the Court's request, but it adamantly objected because the record was complete. Since my impression is that BCBS was more concerned with closing this matter, than reviewing the alleged experimental nature of this device, BCBS shall accept and review any new preauthorization request made by Plaintiff as soon as possible.

477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence "is to be believed and all justifiable inferences are to be drawn in his favor." *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004) (quoting *Anderson*, 477 U.S. at 255).

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Twp., 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorp., 912 F.2d 654, 657 (3d Cir. 1990); see also Fed. R. Civ. P. 56(e) (requiring nonmoving party to "set forth specific facts showing that there is a genuine issue for trial").

ANALYSIS

1. Level of Review

As an initial matter, the parties contest the proper standard of review of BCBS's denial of preauthorization. According to Plaintiff, because BCBS did not reserve discretionary authority, regarding its plan interpretation, the Court should review this matter *de novo*. BCBS, however, contends that the arbitrary and capricious standard is appropriate, since it reserved itself with discretion to review benefits under the Plan.

Under Section 502(a)(1)(B) of ERISA, a plan participant may bring a civil action "to recover benefits due to him [or her] under the terms of the plan." 29 U.S.C. § 1132(a)(1)(B). It is well-established that "a denial of benefits challenged under § 1132(a)(1)(B) is to be reviewed under a de novo standard unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan." Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115 (1989). However, "[w]hen a plan grants its administrator such discretionary authority, trust principles make a deferential standard of review appropriate and we review a denial of benefits under an 'arbitrary and capricious' standard." Fleisher v. Std. Ins. Co., 679 F.3d 116, 120 (3d Cir. 2012) (internal quotation marks and citation omitted). Under this narrow standard of review, "a court can overturn the decision of the plan administrator only if it is without reason, unsupported by substantial evidence or erroneous as a matter of law." Doroshow v. Hartford Life & Accident Ins. Co., 574 F.3d 230, 234 (3d Cir. 2009).

Here, contrary to Plaintiff's assertion, the Plan explicitly reserved BCBS with discretion in reviewing benefits claims. As such, based on the language of the Plan, BCBS is entitled to an arbitrary and capricious standard of review. See Eugene S. v. Horizon Blue Cross Blue Shield of N.J., 663 F.3d 1124, 1132 (10th Cir. 2011).

Alternatively, Plaintiff argues that BCBS should be subject to *de novo* review, since it violated ERISA's claim procedure. According to Plaintiff, because her condition required "urgent care," BCBS's denial of preauthorization violated 29 C.F.R. § 2560.530-1, which regulates ERISA's claims administration. Under 29 C.F.R. § 2560.530-1(b)(3), a plan's claim procedures is unreasonable if "the denial of a claim for failure to obtain a prior approval . . . could seriously jeopardize the life or health of the claimant." 29 C.F.R. § 2560.530-1(b)(3). Such circumstances,

according to ERISA, include when "the claimant is unconscious and in need of immediate care at the time medical treatment is required." *Id.* In addition under 29 C.F.R. § 2560.503-1(m)(1)(i):

A "claim involving urgent care" is any claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations –

. . .

(B) In the opinion of a physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim.

Id. Here, Plaintiff's condition does not put her life or health in jeopardy. In addition, Dr. Hausman's opinions do not suggest that her claim involves urgent care. In his letters to BCBS, he notes that while Plaintiff is in "considerable pain" she also continues to work full-time. However, at no point does he ever stress the urgency of this procedure or the severity of her condition. In addition, consistent with 29 U.S.C. § 2560.503-1(m)(1)(i)(A)-(B), the Plan provides coverage for such "Medical Emergencies" (The Plan at 39, 88), which Plaintiff did not avail herself of. As such, BCBS did not violate Plaintiff's ERISA's claims procedure.

In sum, given that the Plan reserves BCBS with discretion to review benefit claims and since BCBS's claims procedure is reasonable, the appropriate level of review is arbitrary and capricious.

2. Denial of Preauthorization

Having determined the appropriate level of review, the Court next considers whether BCBS's denial was arbitrary or capricious. Under this standard, "an administrator's decision will only be overturned if it is without reason, unsupported by substantial evidence or erroneous as a matter of law." *Pinto v. Reliance Std. Life Ins. Co.*, 214 F.3d 377, 382 (3d Cir. 2000) (internal quotation marks omitted); *Mitchell v. Eastman Kodak Co.*, 113 F.3d 433, 439 (3d Cir. 1997).

"This scope of review is narrow, and the court is not free to substitute its own judgment for that of the administrator in determining eligibility for plan benefits." *Mitchell*, 113 F.3d at 439. As such, the administrator's decision, "should be upheld even if the court disagrees with it, so long as the interpretation is rationally related to a valid plan purpose and not contrary to the plain language of the plan." *Moats v. United Mine Workers of Am. Health & Ret. Funds*, 981 F.2d 685, 687-88 (3d Cir. 1992) (quoting *Gaines v. Amalgamated Ins. Fund*, 753 F.2d 288, 289 (3d Cir. 1985)).

Here, BCBS's denial of authorization was not arbitrary or capricious. As noted above, the Plan lists a series of tests that it considers when determining whether a proposed procedure is "experimental or investigational." (Plan at 35). Specifically, the Plan states, "[t]here must be sufficient proof, published in peer-reviewed scientific literature that confirms the effectiveness of the Technology. . . . if such proof is not sufficient or is questionable, Horizon BCBSNJ may consider opinions about and evaluations of the Technology from appropriate specialty advisory committees and/or specialty consultants." (*Id.*). Here, as set forth in each of BCBS's denial letters, of principal concern is the fact that the proposed procedure lacks sufficient peer-reviewed literature to support its use. This conclusion was reiterated by two independent doctors, both of whom concurred that the proposed procedure remained investigational at this stage. As such, because the record supports BCBS's determination that the procedure was experimental or investigational, its denial was not arbitrary or capricious.

ORDER

IT IS on this 29 day of May, 2018,

ORDERED that Defendant's Motion for Summary Judgment (ECF No. 16) is GRANTED WITHOUT PREJUDICE; and it is further

ORDERED that Plaintiff's Motion for Summary Judgment (ECF No. 14) is **DENIED**; and it is further

ORDERED that Plaintiff may immediately file another request for her treatment; and it is further

ORDERED that the clerk of the court is directed is to close the case.

Peter G. SHERIDAN, U.S.D.J.